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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,932	07/18/2003	Subhashis Banerjee	117813-18705	3572

87501 7590 04/16/2010

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
04/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,932	BANERJEE ET AL.	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,10-14 and 18-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10-14 and 18-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/09 (3 pages); 12/17/09 (4 pages)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 December 2009 has been entered.

2. Claims 1-7, 9 and 15-17 are cancelled.

Claim 44-48 have been added.

3. Claims 8, 10-14 and 18-48 are pending and under consideration.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Rejections.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 17 December 2009 (4 pages) has been considered by the examiner. A signed and initialed copy of the IDS is included with the instant Office Action. It is noted that references A5 and B1 listed on the IDS are duplicate citations of references cited on the PTO-892 mailed 9/6/06 and as such have been crossed out on the IDS to avoid delays at the time of issue. Applicants' cooperation is requested in avoiding duplicate citations in the interest of compact prosecution.

7. The information disclosure statement filed 17 December 2009 (3 pages) fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure

statement has been placed in the application file, but the information referred to therein has not been considered.

Additionally, applicant is advised that copending US Application serial numbers are not valid U.S. Patents or U.S. Patent application publications and should be listed as non-patent literature on the IDS.

Rejections Withdrawn

8. The provisional rejection of claims 8, 10-14, 18-26 and 28-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 11/233,252 (***allowed, not yet issued***) in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is withdrawn in view that USSN 11/233,252 has now issued as U.S. Patent 7,588,761 and in view of the new grounds of rejection below over U.S. Patent 7,588,761 (***item no. 17 below***).

Rejections Maintained and New Grounds of Rejections

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The rejection of claims 8, 10-14, 18-26, 28-43 and now applied to newly added claims 44-48 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 12/17/2009 maintains the position that one of ordinary skill in the art would not have a reasonable expectation of success that human TNFα antibodies and antigen-binding fragments thereof would be effective at treating psoriasis based on the teachings of Oh et al. Applicants' position is based on the fact that neither Salfeld nor Keystone teach or suggest that the human TNFα antibody (D2E7) and antigen-binding fragments thereof would be effective at treating psoriasis and the dosing regimen for infliximab is not the same for

rheumatoid arthritis and psoriasis. Applicant reiterates that the examiner has not established how the claimed methods were selected from a finite number of identified, predictable solutions, as required under the guidelines set forth under MPEP 2143 (E) for establishing obviousness under the "obvious to try" rationale. Applicant states that there exists a limitless number of dosage amounts that can be used in any given treatment as there also exists a limitless dosing schedule in terms of how frequently an agent may be delivered. Applicants' arguments have been fully considered but are not found persuasive. Applicants' argument that one of ordinary skill in the art could not predictably extrapolate the dosing regimen for the fully human anti-TNFα antibody D2E7 in the treatment of rheumatoid arthritis as taught by Keystone et al to the treatment of psoriasis, given that the dosing regimen for infliximab is not the same for rheumatoid arthritis and psoriasis is not found persuasive because applicant is relying upon information in which different dosing is used to achieve a desired therapeutic effect for different disorders (e.g., infliximab dosing for rheumatoid arthritis vs. psoriasis) as opposed to showing that differences in dosing are unpredictable and that different dosing would have provided no reasonable expectation of success. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). That is, the evidence merely shows that different dosing regimens may be required to achieve a desired therapeutic effect, not that the different dosing regimens would not be effective and lack a reasonable expectation of success. Further, applicant has not established a nexus between infliximab and the fully human anti-TNFα antibody D2E7 such that one of ordinary skill in the art would accept that infliximab is predictive of the fully human anti-TNFα antibody D2E7. Further, even if one of ordinary skill in the art would find that the different dosing regimens for infliximab in the treatment of rheumatoid arthritis and psoriasis is predictive of other neutralizing anti-TNFα therapeutic agents, particularly the fully human anti-TNFα antibody D2E7, the teachings of Keystone et al provide a starting point from which to begin dosing experiments to determine the optimal dosing of fully human anti-TNFα antibody D2E7 for the treatment of psoriasis. The teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Again, "[A] person of ordinary skill has good reason to pursue the known options within his or her technical

grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397.

Applicants' arguments that the citation of *In re Aller* is not on point because the claimed invention is not an optimization of a known process is acknowledged, however, the examiner cited M.P.E.P. § 2144.05 II.B and *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) and *In re Aller* to make the point that, in general, the optimization of an art-recognized results-effective variable such as adjusting dosing regimens to provide the optimum desired response would have been obvious and cannot be the basis for patentability. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 716.02 - § 716.02(g) for a discussion of criticality and unexpected results. To the extent that applicant is arguing that *In re Aller* is inapplicable because the claimed invention is not an alteration of a range, applicant is reminded that the instant claims are directed to dosage ranges at which the antibody is administered. Further, applicants' arguments regarding *In re Aller* are curious given that the focus of applicants' rely as well as previous replies are directed to differences in dosing regimens, rather than the discovery that human TNFα antibodies or antigen-binding portions thereof may be used to treat psoriasis on which applicant asserts that the instant invention is based, yet not argued (top of pg. 10 of the reply filed 12/17/09).

Applicants' arguments that there exists a limitless number of dosage amounts that can be used in any given treatment as there also exists a limitless dosing schedule in terms of how frequently an agent may be delivered have been fully considered but are not found persuasive. Applicants' arguments overlook the teachings of Keystone et al, which indicate that subcutaneous biweekly administration of the fully human anti-TNFα antibody D2E7 at 20 mg, 40 mg and 80 mg, albeit for the treatment of *rheumatoid arthritis*, was well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, while one of ordinary skill in the art would recognize that the optimal dosing regimen for the D2E7 antibody may vary

for the treatment of other TNFα-mediated disorders, such as psoriasis as taught by Oh et al, given the success of D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly), one of ordinary skill in the art would have been motivated to at least administer the D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week for the treatment of psoriasis. "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. Thus, consistent with MPEP 2143(E), the teachings of Oh et al provide an effective therapy for treating psoriasis using an anti-TNFα antibody, thereby establishing a recognized problem or need in the art and a predictable potential solution to the recognized need or problem and one of ordinary skill in the art could have pursued the known subcutaneous biweekly administration of the known fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al at 20 mg, 40 mg and 80 mg for the treatment of psoriasis, since the teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, when considering the teachings of the references relied upon in the rejection, it is unclear how subcutaneous administration at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly) of the known fully human anti-TNFα antibody D2E7 of Salfeld et al [a] and Keystone et al represents a limitless number of dosage amounts and dosing schedule that can be used.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

11. The rejection of claims 8, 10-14, 18-26, 28-43 and now applied to newly added claims 44-48 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) in view of Salfeld et al [b] (US Patent 6,509,015 B1, 2/9/1996, cited on PTO-892 mailed 9/6/06) and

Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 12/17/2009 argues as above and the examiner's remarks above apply here as well and are incorporated herein by reference. It is noted that the instant rejection differs only in the use of Salfeld et al [b], however, Salfeld et al [a] and [b] are equivalent teachings.

Therefore, as discussed supra the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

12. The rejection of claims 8, 10, 12 and 27 under 35 U.S.C. 103(a) as being unpatentable over Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) and Neuner et al (Photochem Photobiol., 59(2):182-188, Feb 1994) is maintained.

The response filed 12/17/2009 argues as above that the combined teachings of Oh et al, Salfeld et al and Keystone et al do not establish a *prima facie* case of obviousness and the teachings of Neuner et al do not make up for the deficiencies in Oh et al, Salfeld et al [a] and Keystone et al. Applicants' arguments have been fully considered but are not found persuasive. The examiner's remarks above apply here as well and are incorporated herein by reference.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. The provisional rejection of claims 8, 10-14, 18-26, 28-43 and now applied to newly added claims 44-48 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-10, 16-21, 78-79, 81, 84, 86-88, 95, 97-98 and 100-104 of copending Application No. 10/163,657 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 12/17/2009 states that the rejection is provisional in nature and will be addressed when appropriate, i.e., when the nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP 804 I.B.). Applicants' remarks are acknowledged, however, in view that the claims are rejected on other grounds and not presently in condition for allowance, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 10/163,657, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

15. The provisional rejection of claims 8, 10-14, 18-25, 28-43 and now applied to newly added claims 44-48 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 9-22, 25-26 and 28-53 of copending Application No. 11/104,117 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000) is maintained.

The response filed 12/17/2009 states that the rejection is provisional in nature and will be addressed when appropriate, i.e., when the nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP 804 I.B.). Applicants' remarks are acknowledged, however, in view that the claims are rejected on other grounds and not presently in condition for allowance, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/104,117, discussed above, would form the basis for a rejection of the noted claims under 35

U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

16. The rejection of claims 8, 10-14, 18-25, 28-43 and now newly added claims 44-48 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 36-39 and 69-70 of U.S. Patent No. 6,509,015 B1 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-8892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08) is maintained.

The response filed 12/17/2009 argues as above, i.e., the combined teachings of Salfeld et al, Oh et al and Keystone et al do not provide a reasonable expectation of success for the treatment of psoriasis with biweekly, subcutaneous dosage regimen of human anti-TNFα antibody as presently claimed. Applicants' arguments have been fully considered but are not found persuasive for the reasons set forth above and incorporated herein by reference, and in view that no terminal disclaimer has been filed.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common

ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

17. Claims 8, 10-14, 18-26 and 28-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 in view of Oh et al (Journal of the American Academy of Dermatology, 42(5):829-830, 2000, cited on PTO-892 mailed 9/6/06) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, cited on PTO-892 mailed 9/6/06) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic,* 2001, IDS reference C62 filed 5/28/08).

Claims 16, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 are drawn to a method for treating a subject suffering from various disorders in which TNFα activity is detrimental comprising administering a pharmaceutical composition comprising an isolated human anti-human TNFα antibody or antigen-binding fragment thereof that dissociates from human TNFα with a K_d of 1 x 10^{-8} M or less and has a K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance, and neutralizes human TNFα cytotoxicity in a

standard *in vitro* L929 assay with an IC_{50} of 1 x 10^{-7} M or less, or wherein the antibody is D2E7 or an antigen-binding portion thereof and wherein the composition is administered in combination with at least one additional therapeutic agent. Claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 do not specifically teach biweekly, subcutaneous administration of a unit dosage form comprising 10-150 mg, 20-80 mg or about 40 mg of a human anti-human TNFα antibody or antigen-binding fragment thereof for the treatment of psoriasis in a human patient, wherein the antibody comprises the light chain variable region of SEQ ID NO:1 and the heavy chain variable region of SEQ ID NO:2 or wherein the at least one additional therapeutic agent is selected from a topical corticosteroid, a vitamin D analog and a topical or oral retinoid. These deficiencies are made up for in the teachings of Oh et al and Salfeld et al [a] and Keystone et al.

Oh et al teach a method of treating psoriasis in a patient comprising administering a therapeutically effective amount of a humanized anti-TNFα monoclonal antibody (Infliximab) (see entire document).

Salfeld et al [a] teach that because humanized antibodies still retain some of murine sequence, they still may elicit an unwanted immune reaction in human patients and Salfeld et al [a] teach a method for treating TNFα-related disorders in a subject comprising administering a therapeutically effective amount of the neutralizing, high affinity fully human D2E7 anti-human TNFα antibody or antigen-binding fragment thereof identical to the claimed human anti-human TNFα antibodies, i.e., dissociates from human TNFα with a K_d of 1 x 10^{-8} M or less and has a K_{off} of 1 x 10^{-3} s^{-1} or less, as determined by surface plasmon resonance, and neutralizes human TNFα cytotoxicity in a standard *in vitro* L929 assay with an IC_{50} of 1 x 10^{-7} M or less, and wherein the human antibody or antigen-binding fragment thereof comprises a light chain variable region comprising SEQ ID NO:1 and a heavy chain variable region comprising SEQ ID NO:2 and is administered with one or more additional therapeutic agents, including corticosteroids (see entire document, particularly pp. 2-4, 5-6, 12-15, 29-31 and 35-40). Salfeld also teaches a variety of administration regimens, routes of administration, antibody fragments, antibody heavy chain constant regions, and dosages, such as 0.1-20 mg/kg (see entire document, in particular pp. 33-34). Salfeld also teaches that "[d]osage regimens may be adjusted to provide the optimum

desired response (e.g., a therapeutic or prophylactic response). For example, a single bolus may be administered, several divided doses may be administered over time or the dose may be proportionally reduced or increased as indicated by the exigencies of the therapeutic situation… It is to be further understood that for any particular subject, specific dosage regimens should be adjusted over time according to the individual need and the professional judgment of the person administering or supervising the administration of the compositions, and that dosage ranges set forth herein are exemplary only and are not intended to limit the scope or practice of the claimed composition (see pp. 33-34). Thus, according to the teaching of Salfeld, *the dosage regimen for anti-TNFα antibody, including dosage scheduling and amount, is a recognized results-effective variable,* i.e., a variable that is recognized as important for therapeutic use of an anti-TNFα antibody and which therefore can be optimized by routine experimentation. See M.P.E.P. § 2144.05 II.B. and *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Keystone et al teach that the fully human anti- TNFα antibody D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly) was well tolerated and therapeutically effective, particularly at 40 mg every other week (see entire document).

The claims in the instant application are obvious variants of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 because it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a method for treating psoriasis in a human subject comprising biweekly, subcutaneous administering the human D2E7 anti-human TNFα antibodies of Salfeld et al [a] at 20 mg, 40 mg or 80 mg (particularly 40 mg) with a corticosteroid for the treatment of psoriasis in a patient.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to produce a method for treating psoriasis in a human subject comprising biweekly, subcutaneous administering the human D2E7 anti-human TNFα antibodies of Salfeld et al [a] at 20 mg, 40 mg or 80 mg (particularly 40 mg) with a corticosteroid for the treatment of psoriasis in a patient. in view of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 and Oh et al and Salfeld et al [a] and Keystone et al because Oh et al teach a method of treating psoriasis in a patient comprising administering a therapeutically effective amount of a humanized anti-TNFα

monoclonal antibody (Infliximab), however, Salfeld et al [a] teach that because humanized antibodies still retain some of murine sequence, they still may elicit an unwanted immune reaction in human patients and Salfeld et al [a] teach the neutralizing, high affinity fully human D2E7 anti-human TNFα antibody and antigen-binding fragments thereof for treating TNFα-related disorders in a subject comprising administering a therapeutically effective amount of a human anti-human TNFα antibody or antigen-binding fragment thereof identical to the human anti-human TNFα antibodies claimed in the present application and administered with a corticosteroid and Keystone et al teach that the fully human anti-TNFα antibody D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e., biweekly) was well tolerated and therapeutically effective, particularly at 40 mg every other week. Therefore, one of ordinary skill in the art would have been motivated to modify the method of Oh et al using the human D2E7 anti-human TNFα antibodies and antigen-binding fragments thereof of Salfeld et al [a] in order to avoid any unwanted immune reaction in human patients due to the presence of murine sequences in the humanized anti-TNFα antibody of Oh et al and one of ordinary skill in the art would have been motivated to administer the D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week, which is well tolerated and therapeutically effective according to Keystone et al. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a method for treating psoriasis in a human subject comprising biweekly, subcutaneous administering the human D2E7 anti-human TNFα antibodies of Salfeld et al [a] at 20 mg, 40 mg or 80 mg (particularly 40 mg) with a corticosteroid for the treatment of psoriasis in a patient. in view of claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of U.S. Patent No. 7,588,761 and Oh et al and Salfeld et al [a] and Keystone et al.

Claims 8, 10-14, 18-26 and 28-48 are directed to an invention not patentably distinct from claims 6, 26, 41, 51, 61, 66, 80, 90, 100, 110, 119 and 129 of commonly assigned U.S. Patent No. 7,588,761. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 7,588,761, discussed above, would form the basis for a

rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643